UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HALL, THOMAS and DOROTHY, Plaintiffs, v. BRISTOL-MYERS SQUIBB CO., et al., Defendants.	Civil Action No. 06-5203 (FLW)
LABARRE, ELOISE, as surviving spouse and Administratrix of the Estate of Edward Clyde LaBarre, Sr., Deceased. Plaintiff, v. BRISTOL-MYERS SQUIBB CO., et al., Defendants.	Civil Action No. 06-6050 (FLW) **OPINION**

WOLFSON, District Judge:

This matter comes before the Court on two separate motions to dismiss pursuant to Rule 12(b)(6) and Rule 9(b) of the Federal Rules of Civil Procedure brought by defendants Bristol Myers-Squibb Company, Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc., (collectively, "Defendants"). Plaintiffs Dorothy and Thomas Hall[1], husband and wife, and Eloise LaBarre, as surviving spouse and administratrix of the Estate of Edward Cyde LaBarre, Sr.

[1]Because Defendants are not seeking to dismiss Mr. Hall's claim of loss of consortium on this motion, the Court will refer to Mr. and Mrs. Hall as one Plaintiff.

("Decedent") (collectively, "Plaintiffs") bring separate suits against Defendants alleging that they suffered injuries as a result of Defendants' unlawful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and sale of the prescription drug Plavix.[2] In that respect, each of Plaintiffs' First Amended Complaints ("Amended Complaint") asserts various Florida state and common law claims against Defendants. In the present matter, Defendants move to dismiss Count V, i.e., negligent misrepresentation claim and Count VI, i.e., fraud claim pursuant to the Florida Unfair Deceptive Trade Practices Act, asserted by Plaintiffs. For the reasons that follow, Counts V and VI are dismissed without prejudice.

BACKGROUND FACTS

I. Procedural History

Plaintiffs, citizens of Florida, filed two separate complaints against Defendants asserting claims under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, et seq., the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq., the New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.9, et seq., the New Jersey Uniform Commercial Code, N.J.S.A. 12A:2-313 and the common law of the State of New Jersey, invoking this Court's diversity jurisdiction. See Plaintiffs' Complaints, ¶¶ 6-8. Plaintiffs are among the individual claimants[3] that lodged separate complaints[4]

---

[2] Although Plaintiffs bring separate suits against Defendants, this Opinion addresses Defendants' motion as to both Plaintiffs because Plaintiffs assert identical Florida state law claims.

[3] Initially, claims were filed in twenty-four individual cases, however, a Michigan plaintiff in the matter of Felmlee v. Bristol-Myers Squibb Co., No. 06-6240, voluntarily dismissed her claim in February, 2008.

[4] A number of the twenty-three claimants were joined in their actions by spouses asserting claims for loss of consortium.

against Defendants in this district between October 2006 and March 2007, invoking this Court's diversity jurisdiction and asserting similar claims under New Jersey law based upon injuries allegedly suffered as a result of Defendants' alleged negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and/or the sale of Plavix. Id. A brief recitation of the procedural history in the related matters is necessary to a full understanding of the prolonged procedural history in this matter.

In January 2007, Defendants filed motions to dismiss pursuant to Fed.R.Civ.P. 12(b)(6) in the matters of Hall v. Bristol-Myers Squibb, No. 06-CV-5203 (hereinafter, "Hall"), and Skilstaff v. Bristol-Myers Squibb, No. 06-CV-4965 (hereinafter, "Skilstaff")[5], and indicated their intention to file similar motions in the other Plavix cases pending before this Court. In March 2007, this Court, without objection from the parties, administratively terminated Defendants' motions in Hall and Skilstaff having determined that two cases then pending before the New Jersey Supreme Court addressed the central issues to be decided by this Court on Defendants' motions to dismiss. The parties further agreed that all Plavix cases filed in this district be held in abeyance. Following the issuance of the New Jersey Supreme Court's decisions in Rowe v. Hoffman-LaRoche, 189 N.J. 615 (2007), and International Union of Operating Engineers, Local #68 v. Merck, 192 N.J. 372 (2007), the plaintiff in Skilstaff voluntarily dismissed the action and this Court granted Defendants' request to file a single omnibus motion to dismiss applicable to all personal injury Plavix lawsuits then pending in this district.

---

[5] The plaintiff in the matter of Skilstaff v. Bristol-Myers Squibb, is not among the twenty-three individual claimants seeking damages for personal injuries, rather Skilstaff was an Alabama third-party payor seeking certification of a class of third-party payors for violations of the New Jersey Consumer Fraud Act.

One of the main issues to be determined by this Court in the omnibus motion was the federal preemption of the plaintiffs' individual state law claims. In February 2008, however, in light of the fact that the Third Circuit had pending two separate cases, Colacicco v. Apotex, Inc., and McNellis ex. rel. DeAngelis v. Pfizer, Inc., on its docket regarding substantially similar preemption issues, as did the United States Supreme Court, Levine v. Wyeth, this Court administratively terminated the personal injury Plavix cases pending in this district and permitted plaintiffs to re-file amended complaints in the event there were viable claims after the decisions from the Higher Courts. Following the issuance of the Supreme Court's decision in Levine v. Wyeth, __ U.S. __, 129 S.Ct. 1187, 173 L.Ed. 2d 51 (2009), this Court reinstated the closed cases and, on May 1, 2009, each of the plaintiffs filed an amended complaint. In the amended complaints, each individual plaintiff brought claims under the laws of the states in which they reside, rather than New Jersey, as originally plead. Thereafter, Defendants moved to dismiss certain counts of the amended complaint filed by each individual plaintiff. It is the Defendants' motions to dismiss both Plaintiffs' Counts V and VI that this Court now considers.

II. Factual Background

The following version of events assumes Plaintiffs' allegations in their Amended Complaints to be true because Defendants move pursuant to Fed. Civ. R. P. 12(b)(6). The Court will recount only those facts relevant to the present matter.

Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc. (collectively, the "Sanofi Defendants") partnered with Bristol-Myers Squibb Company ("BMS") to manufacture and market Plavix in the United States. See Amended Complaint ("Am. Compl."), ¶¶

2-5.[6] In April 1997, the Sanofi Defendants and BMS applied for a rare, priority regulatory review by the Food and Drug Administration ("FDA") clearing the way for Defendants to bring Plavix to market in November 1997. Id., ¶ 11. According to Plaintiff, Defendants heavily marketed Plavix directly to consumers through television, magazine, and internet advertising, falsely touting Plavix "as a 'super-aspirin' that would give a person even greater cardiovascular benefits than a much less expensive, daily aspirin, while being safer and easier on a person's stomach than aspirin." Id., ¶ 13. Plaintiffs allege that Defendants either knew or should have known, based upon their own studies, that not only was Plavix not more efficacious than aspirin in terms of preventing heart attacks and strokes, the risk of suffering a heart attack, stroke, internal bleeding, blood disorder or death far outweighed any benefit from the drug. Id., ¶ 14.

As evidence that Defendants were indeed aware of their false and misleading promotion of Plavix, Plaintiffs point to a November 1998 letter from the FDA wherein the FDA instructed Defendants to cease promoting Plavix for off-label use in patients undergoing coronary artery stent placement.[7] Id., ¶ 18. Plaintiffs also point to the same FDA reprimand wherein Defendants were instructed to cease promoting Plavix at an off-label dose, which was nearly four (4) times that of the recommended dosage. Id. In addition to criticizing Defendants for promoting Plavix for unapproved use, the FDA also criticized Defendants for overstating the safety profile of Plavix with respect to its use with other drugs. Id., ¶ 19. In particular, Plaintiffs point to the fact that Defendants touted the safety of Plavix when combined with aspirin (known as "dual therapy") when, in fact, its safety

---

[6] Because both Plaintiffs' Amended Complaints are substantially identical, the Court will refer to them collectively, unless otherwise noted.

[7] As discussed more fully infra, the Court will consider the extrinsic documents referenced in the FAC as they were explicitly relied upon by Plaintiff in the FAC.

had not been established. Id. According to Plaintiffs, Defendants' claim regarding the safety of dual therapy has now been proven to be untrue in a recent study published in the New England Journal of Medicine in April 2006 entitled Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance (the "CHARISMA Study"[8]). Id.

As further evidence of Defendants' allegedly false and misleading promotional practices, Plaintiffs point to a December 1998 letter from the FDA, wherein the FDA demanded that Defendants cease the distribution of advertising materials that claimed that Plavix has been proven to be more effective than aspirin. Id., ¶ 20. The FDA criticized Defendants' materials as an overstatement of efficacy, which was unsubstantiated and lacking in fair balance. Id. Again in 2001, the FDA ordered Defendants to immediately cease distribution of promotional material that made false or misleading claims about Plavix. Id., ¶ 21. Specifically, the FDA noted that the clinical evidence of the efficacy of Plavix is derived from Defendants' study entitled Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events Trial (the "CAPRIE Study"). Id. Defendants' promotional material depicted a 19.2% relative risk reduction for Plavix versus aspirin, yet the actual findings of the CAPRIE Study were that Plavix was not proven to be significantly more effective than aspirin. Id. Additionally, the FDA again instructed Defendants to cease claiming that the use of Plavix combined with aspirin was safe and effective. Id.

According to Plaintiffs, in addition to misinforming physicians and consumers through false and misleading promotional materials and advertising, Defendants' drug representatives also misinformed physicians regarding the proper types of patients who should be prescribed Plavix, the

---

[8] The CHARISMA Study derives its name from the Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance trial, which was the subject of the article.

duration of its proper usage and the applications for which Plavix is safe and FDA approved. Id., ¶ 22. Specifically, Plaintiffs point to the fact that the drug representatives have encouraged physicians to prescribe Plavix to a broad population who would receive the same therapeutic benefit from aspirin alone, without the purported risk of death, and to use Plavix for unapproved applications. Id., ¶ 23.

Plaintiffs allege that after a nearly eight-year run of misleading physicians and the public regarding the safety and efficacy of Plavix, scientific studies now reveal that Plavix is in fact dangerous. Id., ¶ 25. Citing a study published in The New England Journal of Medicine in January 2005, entitled Clopidogrel versus Aspirin and Esomeprazole to Prevent Recurrent Ulcer Bleeding (the "Chan Study"), Plaintiff notes the dangers of Plavix. Specifically, Plaintiffs contend that the Chan Study demonstrates the fallacy of Defendants' assertions that Plavix is safer and more effective for patients suffering from gastrointestinal intolerance to aspirin. Id., ¶ 26. Plaintiffs point out that the Chan Study recommended that prescribing guidelines for Plavix be changed so that patients would not erroneously believe that Plavix is safer on the stomach than aspirin, in light of the Study's findings that recurring stomach bleeding was 8.6% in the Plavix group versus only .7% in the aspirin group. Id. Plaintiffs additionally cite to the Chan Study's finding that an aspirin a day plus esomeprazole (the generic name for an inexpensive over-the-counter proton pump inhibitor such as Prilosec) is far more cost effective than paying for the four-dollar per day Plavix pill, which greatly increases the risk of stomach bleeding. Id., ¶27. Finally, citing the CHARISMA Study, Plaintiffs contend that Plavix plus aspirin ("dual therapy") is only minimally more effective than aspirin plus placebo at preventing atherothrombotic events, and more significantly, does more harm than good in those patients without peripheral arterial disease or acute coronary syndrome in that it poses a 20%

increased risk to the patient of suffering bleeding injuries, heart attacks, stroke and death. Id., ¶ 28.

Due to these alleged illegal practices, each Plaintiff asserts, inter alia, a fraud claim pursuant to the Florida Unfair Deceptive Trade Practices Act ("UDTP" and the "Act"), and a Florida state common law claim of negligent misrepresentation; these claims are the subject of this motion. In connection with these two claims, Plaintiff Hall alleges that she "was prescribed used Plavix from December 20, 2002 until October 4, 2005 for the purpose of preventing a heart attack or stroke." Plaintiff Hall further alleges that "[o]n or around November 18, 2004 and again on or around October 2, 2005, plaintiff Dorothy Hall suffered two (2) separate strokes, each requiring medical treatment and attention." See Hall Amended Complaint, ¶¶ 30-31 (hereinafter referred to as "Hall Compl.").

In a similar fashion, Plaintiff LaBarre alleges that Decedent "began taking Plavix in combination with aspirin - "dual therapy" - in November 2002, after he had bypass surgery with stent placement to repair a blockage . . . . [Decedent] continued on the dual therapy of Plavix plus aspirin until on or about December 19, 2004, when he collapsed at home, having suffered a serious intracranial bleeding injury." Plaintiff LaBarre further alleges that Decedent was subsequently put on life support and "remained on life support for two days but physicians were not able to save his life." Decedent was pronounced dead on December 21, 2004. See LaBarre Amended Complaint, ¶ 30 (hereinafter referred to as "LaBarre Compl.").

As result of the alleged injuries, Plaintiffs, in Count VI of their respective Amended Complaints, allege that Defendants violated the UDTP by making "misrepresentations, and/or knowing concealment, suppression, or omission of material facts with the intent that others rely upon the concealment, suppression, or omission in connection with the sale or advertisement of

merchandise or services by Defendants . . . ." Hall Compl., ¶ 105, LaBarre Compl., ¶ 104. In that connection, Plaintiffs allege that "Defendants knew and should have known, that Plavix was unreasonably dangerous and defective, and had a propensity to cause serious and potentially life threatening side effects." Hall Compl., ¶ 99, LaBarre Compl., ¶ 98. Specifically, Plaintiffs allege that "Defendants' practice of promoting Plavix placed and continues to place all consumers of Plavix at risk for serious injury resulting from its potentially lethal side effects." Hall Compl., ¶ 102, LaBarre Compl., ¶ 103. Plaintiffs further allege that "Defendants' statements and omissions were made with the intent that the Plaintiff [and Decedent], and [their] prescribing physician[s], would rely on them." Hall Compl., ¶ 103, LaBarre Compl., ¶ 102. As a result of the alleged illegal practices, Plaintiffs claim that they have "suffered ascertainable loss-economic loss that includes the purchases of Plavix and additional out-of-pocket healthcare related costs, for which the Defendants are liable to the Plaintiff[s] for treble Plaintiff[s'] actual damages." Hall Compl., ¶ 106, LaBarre Compl., ¶ 105.

Similarly, Count V alleges that "Defendants falsely represented to Plaintiff [and Decedent] in direct to consumer advertising and indirectly through misrepresentations to the prescribing physician[s], that Plavix was safe and effective. The representations by Defendants were in fact false and Plavix was not safe and was in fact dangerous to Plaintiff's [and Decedent's] health." Hall Compl., ¶ 75, LaBarre Compl., ¶ 74. Each Plaintiff claims that "[a]t the time the representations were made, Defendants concealed from Plaintiff [and Decedent] and [their] prescribing physician[s] information about the propensity of Plavix to cause great harm." Hall Compl., ¶ 76, LaBarre Compl., ¶ 75. In that regard, Plaintiffs allege that "Defendants' misrepresentations were made by Defendants with the intent to induce Plaintiff [and Decedent] to use Plavix, to [their] detriment."

Hall Compl., ¶ 78, LaBarre Compl., ¶ 77. Plaintiffs further allege that "Defendants' misrepresentations were made to Plaintiff [and Decedent], as well as the general public. Plaintiff [and Decedent] and [their] healthcare provider justifiably relied on Defendants' misrepresentations and consequently, Plaintiff's [and Decedent's] ingestion of Plavix" were to their detriment. Hall Compl., ¶ 82, LaBarre Compl., ¶ 81.

Defendants move to dismiss Count V, the negligent misrepresentation claim, and Count VI, the UDTP claim, of both of Plaintiffs' Amended Complaints. The Court will now address the sufficiency of these claims.

DISCUSSION

I. Standard of Review

When reviewing a motion to dismiss on the pleadings, courts "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008) (citation and quotations omitted). In Bell Atlantic Corporation v. Twombly, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), the Supreme Court clarified the 12(b)(6) standard. Specifically, the Court "retired" the language contained in Conley v. Gibson, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Id. at 561 (quoting Conley, 355 U.S. at 45-46). Instead, the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." Id. at 555. As the Third Circuit has stated, "[t]he Supreme Court's Twombly formulation of the pleading standard can be

summed up thus: 'stating … a claim requires a complaint with enough factual matter (taken as true) to suggest' the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element." Phillips, 515 F.3d at 234 (quoting Twombly, 127 S.Ct. at 1965).

In affirming that Twombly standards apply to all motions to dismiss, the Supreme Court recently explained the principles. "First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009); Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009).[9] "Second, only a complaint that states a plausible claim for relief survives a motion to dismiss." Id. at 1950. Therefore, "a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." Id. Ultimately, "a complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to 'show' such an entitlement with its facts." Fowler, 578 F.3d at 211.

Before reaching the merits of Plaintiffs' claims, there is a threshold procedural question as to the documents and exhibits this Court may consider on this motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6). As previously referenced in this Court's discussion of the Factual Background, Plaintiffs supply this Court with several exhibits, including: (1) a December 1998 FDA letter addressed to Sanofi Pharmaceuticals, Inc.; (2) a copy of the CHARISMA Study; (3) a November

---

[9] The Court notes that because the briefing in this matter was filed shortly after the United States Supreme Court's decision in Ashcroft, counsel for Defendants moved for leave to file supplemental briefing addressing the standard of review applicable to the instant motion. This Court found additional briefing unnecessary and, accordingly, denied Defendants' request.

1998 FDA letter addressed to Sanofi Pharmaceuticals, Inc.; (4) a May 2001 FDA letter addressed to Sanofi-Synthelabo Inc.; (5) the Chan Study; and (6) a Mediation Letter dated March 12, 2009. Additionally, Defendants provide the Court with the November 17, 1997 approval letter for Plavix. While generally a court may not consider matters outside the pleadings when ruling on a motion to dismiss, documents that are "integral to or explicitly relied upon in the complaint" may indeed be considered without converting a motion to dismiss into a motion for summary judgment. In re Rockefeller Ctr. Props., Inc. Sec. Litig., 184 F.3d 280, 287 (3d Cir.1999) (emphasis and citations omitted). Accordingly, the referenced exhibits are properly before the Court on the instant motion to dismiss.

II. The UDTP Claim

To state a claim under the UDTP, neither party disputes that Plaintiffs must plead with particularity pursuant to Rule 9(b). Indeed, to assert a UDTP claim, the allegations must be pled with the heightened specificity of Rule 9(b). See Fla. Digital Network, Inc. v. N. Telecom, Inc., No. 06-889, 2006 U.S. Dist. LEXIS 61983, at *14 (M.D. Fla. Aug. 30, 2006) (quoting Stires v. Carnival Corp., 243 F. Supp. 2d 1313, 1322 (M.D. Fla. 2002)("'[m]ost courts construing claims alleging violations of the Federal Deceptive Trade Practices Act or its state counterparts have required the heightened pleading standard requirements of Rule 9(b)'"); Acciard v. Whitney, No. 07-476, 2008 U.S. Dist. LEXIS 98131, at *15-16 (M.D. Fla. Dec. 4, 2008).

In Frederico v. Home Depot, 507 F.3d 188 (3d Cir. 2007), the Third Circuit elucidated the heightened pleading standard under Rule 9(b):

> Pursuant to Rule 9(b), a plaintiff alleging fraud must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the "precise misconduct with which [it is] charged." To satisfy this standard, the

> plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation.

Id. at 200 (internal citations omitted); In re Supreme Specialties, Inc. Sec. Litig., 438 F.3d 256, 276-77 (3d Cir. 2006)(the Third Circuit advised that pursuant to Rule 9(b), at a minimum, a plaintiff must support his/her allegations of fraud with all the essential factual background that would accompany "'the first paragraph of any newspaper story' – that is, the 'who what, when, where and how' of the events at issue"(citations omitted)). Moreover, a complaint must do more than assert generalized facts, it must allege facts specific to the plaintiff. Rolo v. City Investing Co. Liquidating Trust, 155 F.3d 644, 658-59 (3d Cir. 1998)(where the complaint failed to allege "what actually happened to either" of the plaintiffs, the complaint did not plead "fraud with the specificity required by Rule 9(b)"). This type of heightened pleading requirement is in accord with the Seventh Circuit precedent. DiLeo v. Ernst & Young, 901 F.2d 624, 627 (7th Cir. 1990).

The UDTP is intended to "protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." § 501.202(2); see also Delgado v. J.W. Courtesy Pontiac GMC-Truck, Inc., 693 So. 2d 602, 605-06 (Fla. Ct. App. 2d 1997)(discussing the purpose of DUTP in light of its legislative history). A deceptive practice is one that is "likely to mislead" consumers. Davis v. Powertel, Inc., 776 So. 2d 971, 974 (Fla. Ct. App. 1st 2000). An unfair practice is "one that 'offends established public policy' and one that is 'immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers.'" Samuels v. King Motor Co. of Fort Lauderdale, 782 So. 2d 489, 499 (Fla. 4th DCA 2001) (quoting Spiegel, Inc. v. Fed. Trade Comm'n, 540 F.2d 287, 293 (7th Cir. 1976)); see also Rollins, Inc. v. Butland, 951 So. 2d 860, 869

(Fla. Ct. App. 2nd 2006).

The Florida statute affords civil private causes of action for both declaratory and injunctive relief and for damages. With respect to the recovery of damages, the DUTP provides:

> In any action brought by a person who has suffered a loss as a result of a violation of this part, such person may recover actual damages, plus attorney's fees and court costs as provided in s. 501.2105. However, damages, fees, or costs are not recoverable under this section against a retailer who has, in good faith, engaged in the dissemination of claims of a manufacturer or wholesaler without actual knowledge that it violated this part.

§ 501.211(2). Thus, in order to successfully assert a claim for damages under DUTP, a plaintiff must sufficiently plead three elements: (1) a deceptive act or unfair practice; (2) causation; and (3) actual damages. See Chicken Unlimited, Inc. v. Bockover, 374 So. 2d 96, 97 (Fla. Ct. App. 2d 1979); Gen. Motors Acceptance Corp. v. Laesser, 718 So. 2d 276, 277 (Fla. Ct. App. 4th 1998); Macias v. HBC of Fla., Inc., 694 So. 2d 88, 90 (Fla. Ct. App. 3d 1997).

Moreover, the DUTP requires proof of causation. § 501.211(2). Therefore, in order to prove liability under DUTP, the Court must determine that Plaintiff and Decedent were exposed to Defendants' advertising and marketing materials alleged to constitute a deceptive trade practice and if exposed, the advertising and marketing materials caused Plaintiff and Decedent actual damage. See Montgomery v. New Pipper Aircraft, Inc., 209 F.R.D. 221, 229-30 (S.D. Fla. 2002).

In their Amended Complaints, Plaintiffs allege a unified course of fraudulent conduct and they rely entirely on that as the basis of their UDTP claims. More specifically, as noted above, Plaintiffs allege that Defendants "knew or should have known, that Plavix was unreasonably dangerous or defective, and had a propensity to cause serious potentially life threatening side

effects."[10] Plaintiffs further allege that "[d]espite their knowledge, the Defendants omitted material facts in the disclosures they made to the public, the medical community and consumers, including the Plaintiff[s], concerning the use and safety of Plavix." As a result, Plaintiffs allege that Defendants violated the UDTP by making deceptive and false representations and misrepresentation of material fact and concealed, suppressed or omitted material facts from the public, including Plaintiff and Decedent, concerning the use and safety of Plavix . Plaintiffs' allegations fall short of complying with Rule 9(b).

Arguing the contrary, Plaintiffs maintain that their Amended Complaints assert sufficient facts to satisfy Rule 9(b). In particular, Plaintiffs point to ¶¶ 19-22, 27, 29-30 and 87-111 of their Amended Complaints to support their assertion that they have pled the so-called "newspaper requirements" of Rule 9(b). Summarizing their points, Plaintiffs state (1) that they have alleged who made the misleading statements - Defendants; (2) that they have alleged what was misleading about Defendants' statements - Defendants advertised Plavix as safe and effective in "dual therapy" treatments, off-label use, and more effective than aspirin; (3) that they have alleged that Defendants' statements were known to be misleading or should have been known when made - multiple FDA warnings against deceptive advertising of Plavix's safety and use in certain treatments, as well as scientific studies, both internal and external, refuting Defendants' wrongful advertising of Plavix; (4) that they have alleged what Defendants' misrepresentations were - the safety and effectiveness of Plavix as advertised in the face of both FDA warnings to the contrary and numerous scientific studies; and (5) that they have alleged why Defendants' misrepresentations were misleading -

[10] Since the Court is restating these allegations that were previously set forth in this Opinion, the Court will not repeat the citations to the record here.

concealment of the risks associated with the use of Plavix, promotion of the safe and beneficial use of Plavix for off-label use in patients receiving arterial stents, even though the FDA and scientific studies warned against such use. Nevertheless, Plaintiffs also suggest that under the circumstances of this case, because information regarding their allegations of fraud are within Defendants' control, less specificity of pleading is required pending discovery.

Although Plaintiffs have arguably pled with particularity with respect to the first and third elements of a UDTP claim, they have failed to sufficiently plead the second element - causation. Indeed, Plaintiffs made exhaustive allegations regarding Defendants' alleged illegal practices by relying on FDA correspondence and scientific studies; however, the Amended Complaints fail to allege with specificity the connection between Defendants' conduct and Plaintiffs' resultant injury. Plaintiffs' only allegations particular to their circumstances that support their statutory fraud claims can be found in ¶ 30, or ¶ 31, of the Amended Complaints, wherein Plaintiffs set forth when they were prescribed Plavix and the health issues as a result of taking Plavix. These allegations are insufficient to meet the rigors of Rule 9(b).

Plaintiffs fail to identify any specific advertisements Plaintiff Hall and Decedent viewed, how they were misled by these advertisements, how these advertisements affected their prescriptions for Plavix and how these advertisements caused any of their injuries. In other words, both of the Amended Complaints fail to identify which, if any, of the promotional or marketing materials were received, viewed or relied upon by Plaintiff Hall and Decedent, and if they were, when these materials were viewed and how they were relied upon. More simply stated, Plaintiffs have failed to allege any specific facts establishing a connection between the alleged conduct of Defendants and the alleged injury claimed. See Kritley v. Wadekar, No. 05-5383, 2006 U.S. Dist. LEXIS 60309, at

*9-10 (D.N.J. Aug. 25, 2006)("Plaintiffs offer only general, conclusory statements that Plaintiffs purchased pharmaceutical products manufactured by the company that Defendants were officers and directors of, and that Defendants marketed the products using false representations, with fraudulent scienter." Plaintiffs do not allege with particularity any of the facts that would be expected to be within their knowledge: exactly who bought exactly what product when, relying on what false representations made when by whom"); Guilbealt v. R.J. Reynolds Tobacco Co., 84 F.Supp. 2d 263, 269 (D.R.I. 2000)(when a plaintiff claims that a product advertisement or promotion led to injuries, he or she must "identify specific advertising he [or she has] seen and how it ha[s] affected" him or her to comply with Rule 9(b)'s requirements).

Likewise, Plaintiffs fail to allege that Plaintiff Hall and Decedent's physicians personally received a misrepresentation of fact from Defendants and relied upon that misrepresentation in deciding to prescribe Plavix to Plaintiff Hall and Decedent.[11] Rather, Plaintiffs allege only generally that Defendants "omitted material facts in the disclosures they made to the public, the medical community and to consumers, including the Plaintiff[s] [and Decedent], concerning the use and safety of Plavix," and these "statements and omissions were made with the intent that the Plaintiff [and Decedent], and [their] prescribing physician[s], would rely on them." Although the Amended Complaints also allege that Defendants' drug representatives have misinformed physicians about the proper types of patients who should be given Plavix, the duration of its proper usage, and the applications for which it is safe and FDA approved, Plaintiffs have not identified the representatives, what was said, when it was said, to whom it was said and how these statements relate to Plaintiff

[11]Plaintiffs' Amended Complaints do not provide the names of their prescribing physicians.

Hall and Decedent's prescriptions of Plavix.

Moreover, these factual allegations are not the type of facts that are within the control of, and therefore subject to concealment by Defendants. Instead, these important details regarding misrepresentations made to, and relied upon by, Plaintiff Hall and Decedent and their physicians are within Plaintiffs' ken, but are nowhere to be found within their respective Amended Complaint.[12]

The deficiencies of Plaintiffs' Amended Complaints in this context were recently discussed by the court in In re Schering-Plough Corp. Intron/Temodar Consumer Class Action, No. 06-5774, 2009 U.S. Dist. LEXIS 58900 (D.N.J. Jul. 10, 2009) (Chesler, J.) In that case, plaintiffs filed a class action complaint alleging, inter alia, that defendants "engaged in improper and illegal off-label promotion of Intron-A, PEG-Intron, Rebetol and Temodar." Id. at *6. Plaintiffs further alleged that defendants "orchestrated a campaign to illegally market and promote the Subject Drugs for off label uses . . . and, as a result, Plaintiffs paid for drugs at an inflated price or for drugs that they would not have purchased but for the illicit marketing scheme." Id. at *7. Similar to Defendants' response here, the defendants there filed a motion to dismiss, among other claims, plaintiffs' fraud and negligent misrepresentation claims.

---

[12]Indeed, in that connection, each Plaintiff is uniquely equipped to determine from their physician whether the physician received such promotional literature. Even where factual information may be within the domain or control of Defendants, such as the identities of the doctors who received promotional information, Plaintiffs must still "accompany their legal theory with factual allegations that make their theoretically viable claim plausible." In re Burlington Coat Factory, 114 F.3d 1410, 1418 (3d Cir. 1997). Moreover, to "avoid dismissal," a complaint must also delineate at least the nature and the scope of a plaintiff's efforts to obtain, before filing the complaint, the information needed to plead with particularity. Shapiro v. UJB Financial Corp., 964 F.2d 272, 285 (3d Cir. 1992). Plaintiffs have failed to comply with these requirements. Indeed, Plaintiffs' Amended Complaints contain no allegations that the information required for Plaintiffs to meet Rule 9(b) obligation is solely within Defendants' control.

In dismissing these two specific claims, the court, in a well-reasoned opinion, found that plaintiffs made "sweeping allegations" regarding defendants' alleged promotion, yet they did not plead a single instance in which they, themselves, or any of their prescribing doctors received a misrepresentation of fact on which they relied upon in either taking or prescribing any of the subject drugs. Id. at *117. In addition, the court explained that plaintiffs' common law fraud and negligent misrepresentation claims also failed to state a claim because plaintiffs did not allege a causal connection between their injury and defendants' conduct. Id. at *119. While In re Schering-Plough dealt with New Jersey's common law claims, the same reasoning applies here since the fraud theory of that case parallels the instant actions. See Suarez v. Playtex Products, Inc., No. 08-2703, 2009 U.S. Dist. LEXIS 63774, at *8-10 (N.D. Ill. Jul. 24, 2009)(plaintiffs failed to allege with specificity "whether or when they relied on, or even saw, these [misrepresentations] prior to purchasing the coolers"). Accordingly, Plaintiffs fail to inject precision and some measure of substantiation to support their UDTP claim, and therefore, they are dismissed without prejudice.[13]

---

[13] Defendants also contend that Plaintiffs have failed to properly plead their damage claim under the UDTP. For support, Defendants cite various cases that stand for the proposition that actual damages recoverable under the UDTP are limited to the "the difference in the market value of the product or service in the condition in which it was delivered and its market value in the condition in which it should have been delivered according to the contract of the parties." Stires v. Carnival Corp., 243 F. Supp. 2d 1313, 1322 (M.D. Fla. 2002). While Defendants are correct in asserting that Plaintiffs must also plead their damages sufficiently to comply with Rule 9(b), in this case, the Court finds that Plaintiffs have sufficiently pled actual damages. See Hall Compl., ¶¶ 103-109; LaBarre Compl., ¶¶ 102-108. Furthermore, in light of the allegations of fraud on the part of Defendants, Plaintiffs are also permitted under the UDTP to seek punitive damages. See Rollins, Inc. v. Heller, 454 So.2d 580, 585-86 (Fla. Ct. App. 3d 1984)(while the UDTP does not provide for punitive damages, "any award of punitive damages based upon a violation of FDUTPA would be improper absent some independent basis such as fraud"); Urling v. Helms Exterminators, Inc., No. Ax-117, 1985 Fla. App. LEXIS 12462 (Fla. Ct. App. 2d Feb. 18, 1985).

III. Negligent Misrepresentation

The Court notes at the outset that Plaintiffs do not dispute that they must plead with particularity pursuant to Rule 9(b) with respect to their Negligent Misrepresentation claims. Indeed, courts in Florida have required compliance with Rule 9(b) when asserting a negligent misrepresentation claim. See Bailey v. Janssen Pharmaceutica, Inc., No. 06-80702, 2006 U.S. Dist. LEXIS 82811, at *21-22 (S.D. Fla. Nov. 14, 2006); Morgan v. W. R. Grace & Co., 779 So.2d 503, 506 (Fla. Ct. App. 2d 2000).

In Florida, Plaintiffs may establish negligent misrepresentation by proving: "(1) a misrepresentation of a material fact; (2) the representor … [made] the representation without knowledge as to its truth or falsity, or … under circumstances in which [it] ought to have known of its falsity; (3) the representor … intended that the misrepresentation induce another to act on it; (4) injury must result to the party acting in justifiable reliance on the misrepresentation." Hoon v. Pate Constr. Co., Inc., 607 So. 2d 423, 427 (Fla. Ct. App. 4th 1992) (per curiam) (quoting Atlantic Nat'l Bank of Fla. v. Vest, 480 So. 2d 1328, 1331-32 (Fla. Ct. App. 2d 1985)); see also Hasenfus v. Secord, 962 F.2d 1556, 1561 (11th Cir.1992) (negligent misrepresentation).

Here, in order to support their negligent misrepresentation claims, Plaintiffs first allege that "Defendants having undertaken the manufacturing, marketing distribution, and/or promotion of Plavix owed a duty to provide accurate and complete information regrading Plavix." However, breaching that duty, "Defendants falsely represented to Plaintiff [and Decedent] in direct to consumer advertising and indirectly through misrepresentation to the prescribing physician, that Plavix was safe and effective. The representations by Defendants were in fact false and Plavix was not safe and was in fact dangerous to Plaintiff's [and Decedent's] health." Plaintiff further alleges that "[a]t the

time the representations were made, Defendants concealed from Plaintiff [and Decedent] and [their] prescribing physician[s] information about the propensity of Plavix to cause great harm," and thus, "Defendants negligently misrepresented claims regarding the safety and efficacy of Plavix despite the lack of information of the representations' accuracy." Plaintiffs also point to the same allegations used to support their UDTP claims in ¶¶ 19-22, 27, 29-30 and 87-111 of the Amended Complaints to substantiate their claim here.

Viewing the allegations in combination, Plaintiffs have failed to allege with the requisite specificity a claim for negligent misrepresentation. While Plaintiffs may have arguably alleged with specificity elements (1), (2) and (3), Plaintiffs fail to allege specific facts with respect to element (4) of the claim - that the injury must result to the party acting in justifiable reliance on the misrepresentation. In this regard, Plaintiffs' Negligent Misrepresentation claim fails to state a claim for the same reasons why Plaintiffs' UDTP claim fails. No plaintiff-specific facts were pled in connection with this claim. The Amended Complaints fail to allege what specific misrepresentation were made to Plaintiff Hall and Decedent; when they were made to them; the substance of the alleged misrepresentations; the names of their prescribing physician; the substance of the alleged misrepresentation made to their prescribing physician; and when the false representation was made. While the Court does not suggest that Plaintiffs must plead every single fact listed above, Plaintiffs simply do not state with the requisite particularity the circumstances of the alleged fraud or otherwise inject precision into their allegations of how they relied upon Defendants' misrepresentations in connection with taking the prescription drug Plavix. See In re Schering-Plough, 2009 U.S. Dist. LEXIS 58900 at *117-119. Accordingly, Plaintiffs' Negligent Misrepresentation claims are dismissed without prejudice.

CONCLUSION

Based upon the foregoing reasons, Defendants' motions to dismiss Counts V and VI of both Plaintiffs' Amended Complaints are granted. However, Plaintiffs may move separately to amend the Amended Complaint on these counts, but they must cure the deficiencies as outlined by the Court.

DATE: December 30, 2009

/s/ Freda L. Wolfson
The Honorable Freda L. Wolfson
United States District Judge